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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/585,159 | 04/19/2007 | Stig Bengmark | 05822.0338USWO | 8309 |
| 23552 | 7590 | 09/23/2009 | EXAMINER | |
| MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903 | | | | LUKTON, DAVID |
| ART UNIT | | PAPER NUMBER | | |
| 1654 | | | | |
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| 09/23/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/585,159 | BENGMARK ET AL. |
| | Examiner | Art Unit |
| | DAVID LUKTON | 1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 June 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13, 15, 17-20 and 22 is/are pending in the application.
 4a) Of the above claim(s) 9-13, 15, 17-20 and 22 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-3, 5, 7 and 8 is/are rejected.
 7) Claim(s) 4 and 6 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/25/06</u> . | 6) <input type="checkbox"/> Other: _____ . |

Applicants' election of Group 1 (claims 1-8) is acknowledged. Also acknowledged are the elected species:

- a) the cationic polypeptide is polylysine, with a MW of 5-50K;
- b) the anionic polypeptide is polyGlu, with a MW of 5-50K;
- c) water as the specific carrier; and
- d) the elected composition also contains phosphate (buffer).

▲

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Haynes (USP 5,246,707).

Haynes discloses (col 4, line 60+) an equal weight mixture of polyarginine and polyglutamic acid.

Thus, the claim is rendered obvious.

▲

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Nimni (USP 4,378,224).

Nimni discloses (e.g., claims 24 and 44 of the patent) a polyelectrolyte which is either a block copolymer of poly-Lys and poly-Glu, or a mixture of poly-Lys and poly-Glu.

Thus, the claim is rendered obvious.

▲

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Schlenoff (USP 7,101,947).

Schlenoff discloses (col 15, line 8+, and claim 10 of the patent) a mixture that comprises poly-Lys and poly-Glu.

Thus, the claim is rendered obvious.

▲

Claims 1-3, 5, 7, 8 are rejected under 35 U.S.C. §103 as being unpatentable over “Isoelectric Focusing, Principles and Methods”, pages 128-129 (Pharmacia Fine Chemicals, Uppsala Sweden, 1982).

The Pharmacia information brochure on isoelectric focusing discloses what is well known to analytical biochemists, i.e., that marker proteins can be used to assist in the determination

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of the isoelectric point of a given protein. As disclosed, the marker proteins can span a range of isoelectric points, e.g., from pI 4.5 to pI 8.5.

Justification for claims 2 and 3 exists. Claim 2, for example, does not mandate that the amino acids be limited to Arg, His, and Lys, only that at least one of these amino acids must be present. Certainly one or more of these (Arg, His, and Lys) would be present in each of the marker proteins.

Thus, the claims are rendered obvious

▲

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654